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Regulatory imbalance between medicinal and non-medicinal nicotine

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Abstract

Cigarettes are very efficient, but exceedingly 'dirty', nicotine delivery systems. Although nicotine creates dependency, it is the contaminated delivery system that causes tobacco-related harm. With an annual global tobacco market >USD$300 billion, and a large proportion of the >1 billion tobacco users seeking to avoid the 50% risk of death, there should be a huge market for alternative nicotine delivery systems. A move towards risk reduction could significantly benefit public health, provide consumer choice and allow free market forces to combat the leading cause of preventable death. However, market forces are currently prevented from providing consumers with the risk-reducing products they want because of existing regulatory systems. Tobacco products have been exempted from consumer protection laws, but there are no such exemptions for other nicotine delivery products, e.g. NRT. This has resulted in an exceedingly uneven playing field for nicotine products, with the most harmful products subject to little regulation while the least hazardous products are stringently regulated. In effect the world is upside-down, and nicotine regulatory systems should be reformed in order to maximize the reduction in risk. In addition, regulatory bodies need to: develop nicotine- and tobacco-specific expertise, rapidly evaluate which products should be permitted and decide how these products should be marketed. Appropriate regulatory structures could harness the power of free enterprise in global efforts to control the tobacco epidemic. This can be done through the development of regulatory processes designed to ensure that all nicotine delivery products are considered in relative terms (regardless of source), and ensuring that all regulatory action strives for the greatest practical reductions in risk.

Introduction

An estimated 1.1 billion people world-wide currently smoke.[1] If these smokers do not quit, approximately half of them will die prematurely as a direct result of tobacco use,[2] and many others will develop debilitating tobacco-related disease.[3,4] Smoking also has a massive impact on the global economy.[5] Smoking is clearly one of the largest, if not *the* largest, health problems facing society today.

Although nicotine is the psychoactive, addictive drug that maintains tobacco use,[6–8] nicotine *per se* is not considered to cause tobacco-related morbidity and mortality. Rather, it is the process of obtaining nicotine, by inhaling tar and toxic combustion products present in tobacco smoke into the lungs, that causes death and disease.[9] In fact, because tobacco products are very dirty, contaminated nicotine delivery systems, 'clean' nicotine may offer an important means to address this public health disaster.[10] As many of the existing smokers either want to quit smoking, or at least significantly reduce the number of cigarettes they smoke, there is a huge

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potential market for alternative nicotine delivery systems.

Past experience shows that if taxes on tobacco products are increased, many people quit smoking and still more reduce their smoking.[11] This suggests that public policy influences the market for products that facilitate both smoking reduction and cessation. As global sales of cigarettes alone reach approximately $US300 billion a year there is potentially a huge market for products to aid smoking reduction and cessation. However, although there are very few commercial opportunities of this nature, i.e. that would allow tens of millions of lives to be saved while making significant profits for the product manufacturers, this opportunity has not been exploited. The prime reason is that asking smokers to pay some of the money that would otherwise have been spent on cigarettes on an alternative, less hazardous product would violate existing laws in virtually every country around the globe.

Regulation of tobacco products

Although attempts to motivate smokers to quit smoking have been moderately successful, facilitating cessation through 'clean' nicotine-containing products is massively disadvantaged by current regulatory systems. The primary reason is that widespread tobacco use predates consumer protection laws. When consumer protection and drug regulation laws were being developed, the tobacco industry argued with government authorities that if cigarettes were subjected to legislation governing food and drugs, hazardous products or poisons they would effectively be banned, as tobacco products would not be able to meet the required standards. This argument was particularly powerful as many millions of people were already using, and were dependent on, tobacco products.

The logical response of any government would be that if a particular product is so uniquely hazardous that it kills when used as intended, that it has no safe level of consumption, and that it is addictive and therefore cannot be covered under the planned laws, then separate legislation should apply exclusively to tobacco. However, the tobacco industry not only managed to gain exemption from the laws that govern pharmaceutical products, and thus nicotine replacement therapy (NRT), but also managed to prevent the introduction of legislation that would effectively regulate tobacco in any other way.[12] Thus, other than a few minor limitations, there is no control over the manufacture, export, import, marketing, sale or use of tobacco products.

Regulation of nicotine from non-tobacco products

Change in legislation governing tobacco products has taken a long time because there has been tremendous pressure from the tobacco industry to prevent regulation. The overall result is that tobacco products, the most hazardous way of supplying nicotine, kill people when used exactly as directed but remain virtually unregulated. In contrast, nicotine-containing products that can actually save peoples' lives by helping them to reduce or quit smoking, by offering an alternative, clean way of obtaining the nicotine on which they are dependent, are banned in many countries. Even in countries where such products are permitted, they are very heavily regulated.[10]

In addition, while a lack of regulatory constraint allows tobacco companies to introduce new products relatively rapidly, a pharmaceutical product such as NRT can take years from development to marketing approval because of the significant regulatory hurdles which must be cleared under national pharmaceutical laws. Moreover, even after being launched on the market, such products are markedly disadvantaged by restrictions on where and how they can be sold, how the product can be advertised and for what purpose it can be used (usually only short-term use is recommended). These regulatory differences allow tobacco companies to respond very quickly to a changing environment, while a similar change is very difficult for companies marketing NRT products. Furthermore, the economic incentives are far greater for tobacco companies than for those companies developing products to resolve the tobacco epidemic.

The combination of these factors has essentially given traditional tobacco industry products a monopoly on nicotine maintenance. In order to maximize public health benefit, the legal environment surrounding tobacco and NRT must change.

Change within the market

The inequity outlined above would be more acceptable if NRT and tobacco products were targeted at completely different markets. However, as the markets overlap, anything that promotes the use of tobacco products will decrease smoking cessation and smoking reduction. Thus, as tobacco companies keep prices down, heavily advertise tobacco products, promote unrestricted smoking and ensure that tobacco products can be purchased virtually anywhere, cessation rates and sales of NRT will be kept low. In contrast, cessation can be encouraged, particularly among dissonant smokers, by higher taxes on cigarettes, restriction on smoking in public areas, prominent health warnings, better information on how to quit and free-phone quit lines.

Dissonant smokers do not feel good about smoking and want to do something about it. Frequently, this involves switching from regular to 'light' brands of cigarettes, in the belief that there are fewer health risks associated with smoking such cigarettes. Tobacco industry promotion of low-tar brands has been very successful; for example, more than half the cigarettes purchased in the United States in 1995 were low (less than 16 mg) tar.[13] However, in effect, light cigarettes represent consumer deception, as there is a substantial body of evidence indicating that such products do not lower the risk to health.[13–16] The tobacco industry, unlike, e.g. the food industry, is not regulated on the use of the word 'light', and it has been shown that even some 'ultra-light' cigarettes do not deliver substantially reduced levels of tar and nicotine compared to regular cigarettes.[13]

Tobacco companies are continually developing novel products, such as Eclipse and Accord, which can keep dissonant smokers loyal to the tobacco market. Some of these new products no longer qualify for exemption from consumer protection laws and the boundary between 'tobacco' and 'pharmaceutical' products is becoming increasingly blurred.[17] Therefore, it is essential that the regulatory systems are changed. Indeed, in various countries tobacco industry executives are already discussing with governments the type of legislative changes needed in order to market these less hazardous products, and the necessary exemptions that would allow the truth to be told about existing tobacco products.

When the truth about tobacco products is made available to the public, there will be an enormous opportunity to provide consumers with the types of products in which they have already expressed an interest. The total market—those who want to quit, or reduce smoking or to reduce the associated risk, plus those who do not want to expose the people around them to harm—will be enormous.

In addition, hundreds of millions of premature deaths currently result from smoking. Widespread realization of this knowledge presents a major public health opportunity.

As products that can meet this need are introduced, the free market economy will force changes in the market-place. As demand for less toxic nicotine-containing products grows the tobacco industry will be forced to respond, just as implementation of safety features for automobiles in the 1960s forced all manufacturers to comply or risk losing their market share.

The way forward

Given this inequitable regulatory situation, there is a need to level the playing field. However, in order to instigate such changes, the regulatory authorities must be made to recognize scientific and technological progress. In this regard, there is potential for a very strong partnership between public health, medical communities and pharmaceutical companies.

An initial step for the regulatory authorities would be to develop expertise on tobacco and nicotine issues as many of them currently do not have sufficient understanding of these products and how they can be changed. Indeed, some of the recommendations arising from regulatory bodies indicate that they do not realize that nicotine itself is not the problem. Moreover, they do not consider that tobacco products form part of the nicotine market and that NRT is replacing an existing product. There needs to be a method of approving NRT products more rapidly, and it is possible that regulatory authorities can be convinced that applications for NRT products should receive fast-track treatment similar to that granted to HIV therapies.[18] There also needs to be greater reciprocal recognition among different countries, to alleviate the existing situation where products that have already received approval in several markets repeat the entire submission process in every new market.

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